

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

JOSEPH HARRINGTON, individually and on
behalf of all others similarly situated,

Plaintiff,

v.

TETRAPHASE PHARMACEUTICALS, INC.,
GUY MACDONALD, JOHN CRAIG
THOMPSON, and DAVID LUBNER,

Defendants.

DAN SCHLAPKOHL, individually and on behalf
of all others similarly situated,

Plaintiff,

v.

TETRAPHASE PHARMACEUTICALS, INC.,
GUY MACDONALD, JOHN CRAIG
THOMPSON, and DAVID LUBNER,

Defendants.

Civil Action No. 1:16-cv-10133-LTS
(Leave to file granted on 08/17/16)

Civil Action No. 1:16-cv-10577-LTS
(Leave to file granted on 08/17/16)

ORAL ARGUMENT REQUESTED

**REPLY MEMORANDUM IN FURTHER SUPPORT OF DEFENDANTS’
MOTION TO DISMISS THE SECOND AMENDED CLASS ACTION COMPLAINT**

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INTRODUCTION

Plaintiffs' Opposition ("Opp.") fails to defend the sufficiency of the Complaint.¹ For all its rhetoric, the Opposition only underscores that Plaintiffs have not alleged any contemporaneous facts establishing that eravacycline could never be an effective IV-to-oral transition therapy for the treatment of complicated urinary tract infections ("cUTIs"), that the pivotal portion of the IGNITE2 study was doomed to failure, or that any Defendant somehow knew the results of this study months before disclosing them. Nothing in the Opposition overcomes the conspicuous absence of any internal document, report, or communication demonstrating even disagreement about the potential of eravacycline, much less knowledge that it could not be effective. Rather, the Opposition confirms that Plaintiffs base the Complaint almost entirely on misinterpretation of publicly available information and the unsubstantiated opinions of two individuals who have no direct knowledge of the IGNITE2 pivotal study or its results. At best, Plaintiffs have raised the existence of a scientific disagreement about study results, but they cannot escape the long line of cases holding that such disagreements do not give rise to securities fraud claims.

Setting aside Plaintiffs' failure to allege particularized facts as required by Fed. R. Civ. P. 9(b) and the PSLRA, the Court should dismiss the Complaint for other reasons. First, Tetraphase issued explicit, thorough warnings about the uncertainty of its clinical trial of eravacycline. The Opposition's attempt to paint these cautions as "generic" cannot be squared with the Company's meaningful cautionary language. Second, the challenged statements are quintessentially forward-looking as they relate to Tetraphase's *expectations* about the future of eravacycline and

¹ Capitalized terms have the same meaning as ascribed to them in Defendants' Memorandum in Support of Defendants' Motion to Dismiss the Second Amended Class Action Complaint. Dkt. No. 71. All exhibits referenced herein ("Ex.") are attached to the Declaration of Sarah L. Murphy, filed contemporaneously with the Memorandum in Support of Defendants' Motion to Dismiss the Second Amended Class Action Complaint.

the IGNITE2 trial, and are thus protected by the safe harbor of the PSLRA. *See* 15 U.S.C. § 78u-5. Third, the meager facts Plaintiffs cobble together, including stock sales made pursuant to pre-established Rule 10b5-1 trading plans, fail to plead the requisite “strong inference” of scienter.

For these and the other reasons set forth below and in Defendants’ opening memorandum (“Mem.”), the Court should dismiss the Complaint with prejudice.

ARGUMENT

I. Plaintiffs have not pleaded any fact establishing a false statement or omission.

Despite the Opposition’s attempt to water-down the pleading standard (*see* Opp. at 8-9), Plaintiffs are required to plead a *factual basis* for their allegations, not conclusory assertions. *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 193-94 (1st Cir. 1999) (“[P]laintiff must not only allege the time, place, and content of the alleged misrepresentations with specificity, but also the factual allegations that would support a reasonable inference that adverse circumstances existed . . .”) (internal quotation marks omitted); *In re Vertex Pharm. Inc. Sec. Litig.*, 357 F. Supp. 2d 343, 350-51 (D. Mass. 2005) (where “Plaintiffs provide no facts to support their allegation that [defendants’] statements . . . are misleading,” their claims “fail the PSLRA pleading requirements”). As set out below, the Opposition fails to point to any well-pleaded facts to sustain any of Plaintiffs’ three principal claims: that eravacycline “was never going to be an effective IV to oral transition therapy” (Opp. at 12); that Tetrphase’s disclosure of the results from the lead-in phase of IGNITE2 was misleading (Opp. at 13); and that Defendants had the results from the pivotal phase of IGNITE2 by May 2015 but failed to reveal them until months later (Opp. at 13).²

² The absence of any such well-pleaded facts sharply distinguishes this case from those Plaintiffs cite for the proposition that they are not pleading fraud by hindsight. *See* Opp. at 14 n.11. Having failed to establish *contemporaneous* falsity, Plaintiffs at best plead fraud by hindsight. *See Carney v. Cambridge Tech. Partners, Inc.*, 135 F. Supp. 2d 235, 244-45 (D. Mass. 2001) (dismissing omissions claim in part because plaintiffs “alleged no facts indicating that undisclosed, adverse circumstances belying [defendant’s] statements existed”). *See also Ganem*

A. Prior studies of eravacycline do not establish that it could never be an effective treatment.

Both the Complaint and the Opposition identify various pre-Class Period scientific articles which Plaintiffs claim “confirmed [that] Eravacycline would never be an effective oral transition therapy because of its low urine concentration and bioavailability.” Opp. at 12. But Plaintiffs can only advance this argument by engaging in a “subjective, selective, and post-hoc interpretation of scientific articles,” while ignoring the articles’ actual conclusions. *Brennan v. Zafgen, Inc.*, No. 15-13618-FDS, 2016 WL 4203413, at *18 (D. Mass. Aug. 9, 2016). Such a flawed, after-the-fact analysis is irrelevant to the underlying claims at issue in this case. Furthermore, the cited articles, including those Plaintiffs reference for the first time in the Opposition, in fact undermine Plaintiffs’ claims.

For example, Plaintiffs cite a study by Lupton in support of their allegation that “Eravacycline had a low bioavailability and, thus, would not be an effective IV to oral transition therapy.” Opp. at 5 n.4. In fact, the Lupton study concludes just the opposite: the study results “demonstrated that conversion from intravenous to oral eravacycline therapy *is possible*.”³ The Lupton study also concludes that “[t]he utility of eravacycline is further proven in the ability for patients to transition from intravenous to oral therapy . . . without having to change to another agent.”⁴ Similarly, the Opposition cites a 2011 abstract (Opp. at 5 n.5), which notes that eravacycline “showed *promising oral bioavailability* in humans, reaching exposures predicted to

v. InVivo Therapeutics Holdings Corp., No. 15-1544, 2017 WL 74702, at *7 (1st Cir. Jan. 9, 2017) (“The securities laws do not make it unlawful for a company to publicize an aggressive timeline or estimate for a proposed action without disclosing every conceivable stumbling block to realizing those plans.”)

³ Thomas Lupton, *Eravacycline: A Novel Antimicrobial for Complicated Intra-abdominal Infections*, The University of Kansas School of Pharmacy Department of Pharmacy Practice, <https://pharmpractice.ku.edu/journal-club-digest/eravacycline-novel-antimicrobial-complicated-intra-abdominal-infections> (last visited Jan. 11, 2017) (emphasis added).

⁴ *Id.*

be *therapeutically efficacious*.”⁵ The abstract concludes that “[t]he feasibility of development of an oral formulation *was confirmed*.”⁶

Other studies Plaintiffs cite make no comment about the viability of eravacycline as an IV-to-oral treatment for cUTIs or other multidrug-resistant infections. For example, the study by Connors (Opp. at 5 n.4) tested eravacycline using only intravenous dosing and thus concludes nothing about the bioavailability of eravacycline *in oral doses*, let alone that low bioavailability makes eravacycline an ineffective IV-to-oral transition therapy.⁷ Similarly, although a 2014 article by Horcajada (SAC ¶ 52 n.28) states that eravacycline’s “oral bioavailability is poor,” it goes on to suggest that the antibiotic could be effective in treating severe infections.⁸ Finally, one of the more recent articles Plaintiffs cite, a 2016 review of eravacycline by Zhanel (SAC ¶ 34, n.20), notes that eravacycline has low bioavailability, but nonetheless concludes that the drug is “a promising intravenous and oral fluorocycline that may offer an alternative treatment option for patients with serious infections”⁹

At the end of the day, the articles Plaintiffs cite fully support Tetrphase’s view that, throughout the Class Period, eravacycline exhibited the potential to be an effective IV-to-oral

⁵ A. Leighton et al., *Broad-spectrum fluorocycline TP-434 has oral bioavailability in human*, Abstr. P-1509, 21st Eur. Congress of Clinical Microbiology and Infectious Disease, <http://onlinelibrary.wiley.com/doi/10.1111/j.1469-0691.2011.03558.x/epdf> (last visited Jan. 11, 2017) (emphasis added).

⁶ *Id.* (emphasis added). Two additional studies that the Opposition claims confirm that eravacycline would never be effective (Opp. at 12) similarly reach conclusions that in fact support Defendants’ decision to pursue IGNITE2. See Patrick T. Horn et al., *Pharmacokinetics, Safety and Tolerability of a Novel Fluorocycline, TP-434, Following Multiple Dose Oral Administration With and Without Food*, Abstr. 603 Infectious Disease Soc’y Am. 49th Annual Meeting (Oct. 21, 2011), <https://idsa.confex.com/idsa/2011/webprogram/Paper31386.html> (last visited Jan. 11, 2017) (“TP-434 is orally bioavailable, indicating the potential for IV/oral step-down therapy, or oral therapy alone”); Trudy H. Grossman et al., *Eravacycline (TP-434) Is Efficacious in Animal Models of Infection*, 59 *Antimicrobial Agents and Chemotherapy*, no. 5, 2015, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4394802/> (last visited Jan. 11, 2017) (eravacycline’s “demonstrated preclinical and clinical efficacies continue to support eravacycline as a promising new i.v. and oral antibiotic option for the treatment of cIAI, cUTI, and other serious infections”).

⁷ Kevin P. Connors et al., *Phase I, Open-Label, Safety and Pharmacokinetic Study to Assess Bronchopulmonary Disposition of Intravenous Eravacycline in Healthy Men and Women*, *Antimicrobial Agents and Chemotherapy*, American Society for Microbiology, <http://aac.asm.org/content/58/4/2113.full> (last visited Jan. 11, 2017).

⁸ Juan Pablo Horcajada et al., *Future Alternatives for the Treatment of Infections Caused by Carbapenemase-Producing Enterobacteriaceae: What is in the Pipeline?*, 32 *Emerging Infectious Diseases* (Suppl 4), at 59.

⁹ George G. Zhanel et al., *Review of Eravacycline, a Novel Fluorocycline Antibacterial Agent*, 76 *Drugs*, no. 5, at 567, <http://link.springer.com/article/10.1007/s40265-016-0545-8?no-access=true> (last visited Jan. 11, 2017).

transition therapy for the treatment of cUTIs. Otherwise, spending millions of dollars to continue the trial would have made no sense. *See Local No. 8 IBEW Ret. Plan & Trust v. Vertex Pharm., Inc.*, 838 F.3d 76, 82 (1st Cir. 2016) (investment in clinical trial design and performance of clinical study suggest that company “must have thought that positive results were possible”). At most, Plaintiffs’ citations demonstrate scientific disagreement between themselves and Defendants about how to interpret prior clinical trial results and the implications for eravacycline, which does not state a claim for securities fraud. *See* Mem. at 10 (citing cases).¹⁰

Plaintiffs argue that the cited studies report on “objective” metrics and thus show more than a disagreement of scientific opinion. Opp. at 16-17. But Plaintiffs ignore that *all* claims about clinical results, including Plaintiffs’ own, ultimately rest on *interpretation* of “objective metrics” (raw data) – in other words, on opinion. *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015) (“Courts have repeatedly held ‘publicly stated interpretations of the results of various clinical studies’ to be ‘opinions’ because ‘[r]easonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.’”) (quoting *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 567 & n.20 (S.D.N.Y. 2011)).

Plaintiffs also try to distinguish the cases that Defendants cite by asserting that those cases concern disagreement about a study’s methodology or design, as opposed to its results. Opp. at 17 n.13. This is demonstrably not so. *See City of Edinburgh Council v. Pfizer, Inc.*, 754

¹⁰ Plaintiffs correctly note the unremarkable proposition that statements regarding drug efficacy and market potential may be actionable. Opp. at 11. But in their cited cases, unlike here, the plaintiffs pleaded specific facts that contradicted the alleged misrepresentations. *See, e.g., Sanders v. Aveo Pharm., Inc.*, No.13-11157-DJC, 2015 U.S. Dist. LEXIS 35116, at *25 (D. Mass. Mar. 20, 2015) (finding statements regarding trial results misleading where defendants deviated from trial protocol without disclosing the same to investors and FDA had expressed concern with trial methodology); *In re Allaire Corp. Sec. Litig.*, 224 F. Supp. 2d 319, 332 (D. Mass. 2002) (finding statements that product was “fueling growth” and allowing customers to “bring their business to the web faster than ever before” actionable where contemporaneous internal communications and customer email showed the product did not work).

F.3d 159, 170 (3d Cir. 2014) (“These allegations show a difference of opinion within Wyeth about whether the Phase 2 interim results . . . justified initiating a Phase 3 trial. *Interpretations of clinical data are considered opinions.*”) (emphasis added); *Abely v. Aeterna Zentaris, Inc.*, No. 12-cv-4711-PKC, 2013 WL 2399869, at *10-11 (S.D.N.Y. May 29, 2013) (ruling on both the plaintiffs’ claims regarding the study methodology and the study’s findings). The assertion that *Medimmune* supports Plaintiffs’ position (Opp. at 17 n.13) is similarly incorrect. *See In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 967 (D. Md. 1995) (finding statements regarding efficacy actionable *only because* the statements “sweep [in] a representation that the FDA raised no question about the efficacy of the drug,” when in fact the FDA had raised such questions).¹¹

B. Defendants did not mischaracterize the results from the lead-in portion of the IGNITE2 study.

Plaintiffs next argue that the lead-in portion of IGNITE2 confirmed the ineffectiveness of eravacycline insofar as the study “showed a bioavailability of only 28%” (Opp. at 13) and “produced illogical results” (*id.*), and therefore Defendants’ positive characterization of these results was misleading (Opp. at 15-16). This assertion cannot give rise to a securities fraud claim, however, because the question is not who was right on the science but whether the Company concealed any *fact* – and it did not. To the contrary, Tetraphase disclosed the allegedly “illogical” results of the two doses that it tested in the study. *City of Edinburgh*

¹¹ Plaintiffs claim that investors are not required to “become scientific experts” who “deconstruct sophisticated clinical data presented piecemeal throughout numerous third-party documents.” Opp. at 17. Plaintiffs’ citations for this proposition are unavailing soundbites divorced from context. The *Brooks Automation* court assessed when plaintiffs should have reasonably uncovered an options backdating scheme for statute of limitations purposes, but at no point opined on the degree of disclosure the Exchange Act requires regarding scientific data; the decision has not bearing here whatsoever. *In re Brooks Automation Inc. Sec. Litig.*, No. 06-11068-RWZ, 2007 U.S. Dist. LEXIS 88045, at *41 (D. Mass. Nov. 6, 2007). Plaintiffs’ reliance on *Alaska Electric* is similarly misplaced as it again deals with when investors should have uncovered fraud for statute of limitations purposes. *Alaska Elec. Pension Fund v. Pharmacia Corp.*, 554 F.3d 342, 347 (3d Cir. 2009). The court in *SEC v. Mozilo* recognized that the materiality and reliance elements in an SEC enforcement action differ from those in a private class action. No. 09-3994-JFW (MANx), 2010 U.S. Dist. LEXIS 98203, at *29-30 (C.D. Cal. Sept. 16, 2010). Finally, the *Matrixx* court addressed whether adverse event reports in the defendants’ possession were material and warranted disclosure even when they did not rise to the level of statistical significance, concluding that the lack of statistical significance, by itself, did not defeat materiality. *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 30 (2011).

Council, 754 F.3d at 171 (“[T]he disagreement of five employees within a large pharmaceutical company about the interpretation of clinical trial data and the critical strategic decision of initiating an expensive Phase 3 trial does not render defendants’ decisions unreasonable or their statements false.”).¹² Plaintiffs also conveniently ignore that the disclosed study results showed that eravacycline had a better response rate than levofloxacin (Opp. at 6), despite that levofloxacin has higher excretion and bioavailability rates (Opp. at 5) – which further undermines Plaintiffs’ claim that urine concentration and bioavailability alone determine the effectiveness of an oral antibiotic in treating cUTIs (Opp. 5; SAC ¶ 30). As with the prior studies that Plaintiffs cite, these results bolster, rather than refute, the challenged statements about eravacycline’s potential and support the Company’s decision to proceed with the next phase of IGNITE2.

Unable to plead any contemporaneous facts, Plaintiffs rely on the say-so of their confidential witness (“CW1”) and the opinions of Dr. Harald Reinhart, a pharmaceutical consultant and blogger, to argue that the results from the IGNITE2 lead-in study indicated that the drug lacked efficacy. Opp. at 6; SAC ¶¶ 61-62. However, the Opposition does nothing to suggest that CW1 – who has no first-hand knowledge of Tetrphase or IGNITE2 – is credible. Plaintiffs can only claim weakly that CW1’s views must be given weight in light of the supposed “numerous other corroborating allegations in the SAC.” Opp. at 13, n.10. But as explained above, this corroborating evidence does not exist: Plaintiffs point to no document, study, or other

¹² The securities laws do not require that Defendants disparage the disclosed results of the lead-in portion of IGNITE2 by providing any contrary opinion. *See, e.g., Coyne v. Metabolix, Inc.*, 943 F. Supp. 2d 259, 269 (D. Mass. 2013) (“A defendant does not have a duty to cast the descriptions of its business in the most negative light.”). The Opposition’s claim that *No. Nine* “rejected” the “no duty to disparage” argument is simply wrong. Opp. at 16 (citing *In re No. Nine Visual Tech. Corp. Sec. Litig.*, 51 F. Supp. 2d 1 (D. Mass. 1999)). Instead, the *No. Nine* Court merely explained that where a corporation makes a disclosure, it must be complete and accurate. *Id.* at 18. The court went on to explain that “an issuer is only absolved from disclosure where it has provided accurate hard data from which analysts and investors can draw their own conclusions” *Id.* at 18-19 (internal quotation marks omitted). That is precisely what Defendants did here.

piece of evidence showing that, at the time of the allegedly false statements, the pivotal phase of IGNITE2 was doomed to fail. *Cf. In re Cabletron Sys., Inc.*, 311 F.3d 11, 30-31 (1st Cir. 2002) (finding former employees of defendant credible informants where their allegations were detailed, self-verifying, and consistent across multiple informant accounts). Dr. Reinhart fares no better, as he admits that he “cannot claim to have any first-hand information of the data situation, nor vouch for some of the explanations proffered” as to the results of Tetrphase’s “well-designed” pivotal IGNITE2 study.¹³

Plaintiffs also mischaracterize Defendants’ argument that they disclosed all the salient facts about the lead-in phase of IGNITE2 as a “truth on the market” defense. *Opp.* at 14-15. Defendants make no such argument. A truth on the market defense “presupposes the existence of misleading statements in the first place” and urges that revelations of the truth by third parties negate the misleading nature of such statements. *In re Incyte S’holder Litig.*, No. 13-365, 2014 WL 707207, at *10 (D. Del. Feb. 21, 2014) (“[T]here can only be a truth on the market defense if the allegations are first sufficient to establish a fraud on the market.”). Here, Defendants themselves fully disclosed the very results at issue (SAC ¶ 59) and contend that their statements were not misleading. *In re First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145, 155 n.75 (D. Mass. 2009) (“Defendants have not raised a truth on the market defense, but instead argue that Plaintiffs have failed to plead facts to show that there were any misstatements or scienter in the first place.”) (internal quotation marks and citation omitted).

¹³ Harald Reinhart, *After ICAAC: Some More Thoughts on Eravacycline in cUTI and IGNITE-2*, Allphase Pharma Consulting, LLC (Sept. 24, 2015), <http://allphasepharma.com/dir/2015/09/24/1958/after-icaac-some-more-thoughts-on-eravacycline-in-cuti-and-ignite-2> (last visited Jan. 11, 2017). At most, Dr. Reinhart’s opinions show non-actionable scientific disagreement. *See supra* Section I.A.

C. Plaintiffs offer only speculation that Tetrphase received the IGNITE2 pivotal study results by May 2015.

Plaintiffs conspicuously abandon the Complaint's claim that Defendants possessed the pivotal IGNITE2 trial results in April 2015 (SAC ¶¶ 2, 8, 113). Instead, the Opposition now claims that Defendants were aware that the trial failed "[a]s of at least early May 2015" (Opp. at 13). This theory fares no better, as Plaintiffs do not identify a single internal document or Company witness supporting this assertion. The only basis for Plaintiffs' newly minted claim for a May 2015 date of knowledge is that Tetrphase completed enrollment for the pivotal trial in May 2015. Opp. at 13, 35. But the Opposition fails to explain why that matters, given that as of the time of completion of *enrollment*, "there [were] still patients in the study . . . [a]nd the last patient out [would] occur in June." Mem. at 15; Ex. F. Nor do Plaintiffs counter Defendants' argument (Mem. at 16) that analysis of the *data* from the double-blind study, once finally completed, took upwards of six weeks.¹⁴ Accordingly, Plaintiffs have failed to adequately allege that Defendants first learned the results of the study at any time other than when they said they did – in early September 2015 when they disclosed them.¹⁵

II. Plaintiffs have failed to identify any statement that could be actionable.

A. Plaintiffs cannot avoid the PSLRA's safe harbor for forward looking statements.

Plaintiffs first attempt to avoid the PSLRA's safe harbor provision, 15 U.S.C. § 78u-5, by arguing that Defendants' statements concern "present or historical fact directly contradicted by known facts existing at the time of the statements." Opp. at 18. This is a red herring –

¹⁴ The primary endpoint under the trial protocol was the responder outcome in a post-treatment visit taking place 6-8 days after completion of the therapy, meaning Defendants could not possibly have had complete data on the date Tetrphase completed enrollment, let alone had time to analyze it. Ex. D. Moreover, Tetrphase could only analyze data from IGNITE2 after conducting "database lock activities." Ex. F, N. And even further to the point, the study was double-blind, such that Defendants could not interpret any results until the data was unblinded. *See Abely*, 2013 WL 2399869, at *7 & n.3 (taking judicial notice that in double-blind trials "both subjects and investigators, as well as sponsor or investigator staff involved in the treatment or clinical evaluation of subjects, are unaware of each subject's assigned treatment").

¹⁵ This failure also undermines Plaintiffs' argument (Opp. at 14) that Defendants had a duty to update their prior statements once they became aware of the results. Defendants did just that.

Defendants are not asserting that any statement of present or historical fact was forward-looking. Compare Opp. at 18 with Mem. at 16-17 & n.12.¹⁶

Plaintiffs next seek to avoid the PSLRA's safe harbor by claiming that Defendants' statements "regarding the timing of when Tetrphase would report top-line results for the pivotal IGNITE2 trial and submit an NDA" were accompanied only by "boilerplate language." Opp. at 20.¹⁷ The warnings were anything but boilerplate. Tetrphase specifically cautioned that: (a) "[t]he clinical development of eravacycline . . . is susceptible to the risk of . . . failure to achieve efficacy in a trial or across a broad population of patients;" (b) "[t]he outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;" and (c) "although eravacycline achieved favorable results in the lead-in part of our Phase 3 clinical trial in cUTI, we may nonetheless fail to achieve success in our Phase 3 clinical trial for eravacycline for the treatment of cUTI." SAC ¶ 101. These disclosures go far beyond the "boilerplate" warnings found insufficient in other cases. See *In re Ibis Tech. Sec. Litig.*, 422 F. Supp. 2d 294, 311 (D. Mass. 2006) ("[I]t is not necessary for a defendant to describe the particular factor that ultimately causes the forward-looking statement to not come true, as long as the warnings accompanying the statement mention important factors that could cause actual results to differ materially from

¹⁶ In any event, the cases the Opposition relies upon (Opp. at 18-19) are qualitatively different from the case at bar. Cf. *In re Biogen Idec, Inc. Sec. Litig.*, No. 05-10400-WGY, 2007 U.S. Dist. LEXIS 98076, at *9, 30-31 (D. Mass. Oct. 25, 2007) (statements that clinical trial was "clean" and that drug was safe were misleading statements of present or historical fact where the drug had activated a dangerous virus in two clinical patients, leading to one patient's death); *In re Transkaryotic Therapies, Inc. Sec. Litig.*, 319 F. Supp. 2d 152, 160-62 (D. Mass. 2004) (statements that FDA approval is a "when not if proposition" were misleading statements of present or historical fact where the FDA had in fact expressed concern with the clinical trial methodology and opined that the study "could not be salvaged").

¹⁷ Plaintiffs cite *Guerra v. Teradyne, Inc.*, No. 01-11789-NG, 2004 WL 1467065 (D. Mass. Jan. 16, 2004), for the proposition that "simply because a statement is prefaced by 'we believe' does not mean it is automatically forward-looking." Opp. at 19. That may be so, but Defendants nowhere argued that that phrase in and of itself makes any statement forward-looking. To the contrary, the language that followed that "signal," as well as the inclusion of meaningful cautionary language, makes the relevant statement forward-looking. See *Slayton v. Am. Express Co.*, 604 F.3d 758, 769 (2d Cir. 2010).

those in the forward-looking statement.”) (internal quotation marks omitted).¹⁸

Plaintiffs also claim that Defendants’ risk disclosures were themselves insufficient because the risks had already materialized. Opp. at 20-21. But this is just a variation of the flawed mantra that eravacycline’s chemical properties somehow preordained the failure of the IGNITE2 pivotal trial, which, as shown above, Plaintiffs’ own citations contradict.¹⁹

B. Plaintiffs fail to establish that any challenged statements of corporate optimism or opinion are actionable.

The Opposition claims that the challenged statements regarding the expected performance and marketability of eravacycline are not puffery because all are “concrete, verifiable and demonstrably false.” Opp. at 21-22. Whether a statement is puffery, however, has nothing to do with whether the statement is false; the relevant question is whether the statement was sufficiently vague and optimistic so as not to be material in the first instance. *See In re Cytic Corp. Sec. Litig.*, No. 02-12399-NMG, 2005 WL 3801468, at *20 (D. Mass. Mar. 2, 2005) (“Rosy affirmation[s] commonly heard from corporate managers . . . are numbingly familiar. Consequently, no reasonable investor could find such optimistic or vague statements important to the total mix of information.”) (internal quotation marks and citations omitted). Defendants’ statements are precisely the sort of loose expressions of optimism that courts deem inactionable puffery. *Compare* SAC ¶ 89 (“I think there is definitely an opportunity to be in that blockbuster status . . .”), ¶ 103 (describing the Company’s proprietary technology as “a significant

¹⁸ The *Parametric* Court did not, despite Plaintiffs’ contention, “reject[] nearly identical boilerplate warnings.” Opp. at 20. *See In re Parametric Tech. Corp. Sec. Litig.*, 300 F. Supp. 2d 206, 218-19 (D. Mass. 2001) (“While the first part of this notice may be general boilerplate, the last sentence refers to specific factors that might affect Parametric’s revenues in the third quarter of 1998. These were ‘meaningful cautionary statements’ sufficient to invoke the shelter of the safe harbor provision.”). Plaintiffs are similarly wrong that Tetraphase’s cautionary language was insufficiently tailored because it did not change throughout the Class Period. Opp. at 20. As the *Slayton* case on which Plaintiffs rely provides, a problem arises only where the “cautionary language remain[s] the same even while the problem change[s].” *See Slayton*, 604 F.3d at 772-73 (emphasis added). Here, Plaintiffs claim that eravacycline’s chemical properties doomed it to fail from even before the Class Period.

¹⁹ Plaintiffs do not and cannot address Defendants’ explanation in their opening brief that *No. Nine*, 51 F. Supp. 2d at 23-24, is distinguishable because, unlike here, the disclosed risks of past and future but not present shortages within the caution itself could be read to represent that there was no current shortage. *See* Mem. at 20 n.15.

innovation in the creation of tetracycline drugs”), ¶ 104 (“We believe that the ability of eravacycline to cover multidrug resistant Gram-negative bacteria . . . will enable eravacycline to become the drug of choice for first-line empiric treatment”) *with In re Cytoc Corp.*, 2005 WL 3801468, at *25 (statements by defendant that it has a “unique sales and marketing strategy” or that a defendant believed the company was “well positioned for growth” are puffery); *Carney*, 135 F. Supp. 2d at 253 (statement that defendant would be “competitive in the marketplace” was “immaterial corporate puffery or forward-looking statements”); *Van Ormer v. Aspen Tech., Inc.*, 145 F. Supp. 2d 101, 106-07 & n.5 (D. Mass. 2000) (statements such as “[w]e are very pleased with our performance” or “[w]e continue to believe that Aspen is an unusually solid company” are “nothing more than corporate puffery”).²⁰

Plaintiffs also claim that these statements are not puffery because they “convey a comparative connotation.” Opp. at 22 (quoting *Scratchfield v. Paolo*, 274 F. Supp. 2d 163, 175 (D.R.I. 2003)). But the cases cited in the Opposition evaluated statements that courts deemed factual because they concerned the *current* relative market position of an *existing* product, whereas here the statements are softer and merely concern the *potential* market position of a *future* product. See *Scratchfield*, 274 F. Supp. 2d at 175-76 (statement was actionable as a comparison rather than inactionable puffery where defendant suggested that it was the “premier,” “dominant,” or “leading” player in an existing market); *In re Allaire Corp. Sec. Litig.*, 224 F. Supp. 2d at 332 (defendants’ statement that its released software allowed users to “bring their

²⁰ The Opposition also argues that Defendants’ statements are not puffery because they assert or rely on historical facts. Opp. at 22-23. Yet the Opposition neither cites any challenged statement that purportedly does so, nor identifies the past or historical facts purportedly relied on in making any such a statement. In any event, *Smith & Wesson* (see Opp. at 22) does not stand for the proposition that statements *referring to or relying on* historical fact can never be puffery; rather, the case supports the unremarkable proposition that statements of historical fact themselves cannot be puffery. *In re Smith & Wesson Holding Corp. Sec. Litig.*, 604 F. Supp. 2d 332, 342 (D. Mass. 2009).

business to the web faster than ever before” conveyed a comparative connotation and thus was not mere puffery).²¹

The Opposition’s effort to deem actionable Defendants’ statements of opinion is equally unavailing. Plaintiffs concede that certain of the challenged statements are opinion (Opp. at 23), but nonetheless argue that these statements are actionable because: (1) the opinions conveyed “self-embedded facts” that “were contrary to the then existing state of facts” (Opp. at 24 & n.21); and/or (2) the person holding the opinion did not or “had no reason to believe” the statement (Opp. at 24). This argument rests entirely on the flawed narrative that IGNITE2 was doomed to failure, which does not avail Plaintiffs because they have not adequately alleged any fact establishing that eravacycline could never be an effective IV-to-oral treatment for cUTIs (*see supra* Section I.A.) or that any Defendant did not or could not genuinely believe that the pivotal portion of IGNITE2 could meet its primary endpoint (*see infra* Section III.A).²²

²¹ The Opposition further contends that statements that the market considered important cannot, as matter of law, be immaterial puffery (Opp. at 23), but that is completely circular and does not establish that the market considered any of the statements at issue important. Plaintiffs’ reliance on *Bristol-Myers Squibb* (Opp. at 23) is unpersuasive, as there – unlike here – the defendant publicly defined a “blockbuster” product as one reaching over \$1 billion in annual sales, so the statement was objectively verifiable. *In re Bristol-Myers Squibb Sec. Litig.*, No. 00-1990 (SRC), 2005 U.S. Dist. LEXIS 18448, at *101 (D.N.J. Aug. 17, 2005).

²² All of the cases Plaintiffs cite in support of their opinion argument (Opp. at 24-25) are distinguishable on these grounds, as the complaints there included well-pleaded allegations suggesting that the challenged opinions (and/or any facts embedded therein) were contrary to existing facts. *See In re Transkaryotic Therapies, Inc. Sec. Litig.*, 319 F. Supp. 2d at 161-62 (statements of belief in FDA approval were actionable because the FDA had already expressed concern about the clinical trial methodology and opined that the study “could not be salvaged”); *In re Viropharma, Inc., Sec. Litig.*, No. 02-1627, 2003 WL 1824914, at *6 (E.D. Pa. Apr. 7, 2003) (statements reporting clinical trial success actionable because defendants failed to disclose the negative side effects of the drug, various methodological issues, and the inefficacy of the drug in certain populations); *In re Amylin Pharms., Inc. Sec. Litig.*, No. 01-cv-1455-BTM(NLS), 2003 U.S. Dist. LEXIS 7667, at *12-13 (S.D. Cal. May 1, 2003) (statements regarding sufficiency of trials to support FDA approval actionable because defendants failed to disclose that FDA had expressed serious concerns about their study design); *Rosenbaum Capital LLC v. Boston Commc’ns Group, Inc.*, 445 F. Supp. 2d 170, 176-77 (D. Mass. 2006) (statements that company did not believe it infringed patents actionable where company allegedly took steps to hide its willful infringement). Additionally, Plaintiffs’ attempt to distinguish *Cody v. Conformis* (Mem. at 24) fails. Plaintiffs are simply incorrect that the *Cody* plaintiffs did not allege that self-embedded facts within the opinion were untrue. Opp. at 24 n.21. Plaintiffs in *Cody* did make such a claim, and the court rejected it. *See Cody v. Conformis*, No. 15-13295-GAO, 2016 WL 4132204, at *9 (D. Mass. Aug. 3, 2016) (“Nor is there any indication that the purportedly ‘embedded’ statement that Bedford and Burlington ‘are compliant’ is itself factually untrue.”).

III. The Complaint does not support a strong inference of scienter.

Even if the Complaint had adequately alleged that Defendants made false or misleading statements concerning eravacycline or IGNITE2 – which it has not – these claims still fail because Plaintiffs’ scienter theory does not approach the realm of “cogent and compelling.” Plaintiffs principally argue that the Individual Defendants knew that eravacycline was not and would never be an effective IV-to-oral transition therapy, and knew months in advance that the IGNITE2 trial had failed, but concealed this information in order to profit from stock sales. Opp. at 26. But as shown above, *supra* Sections I.A.-B., there is no basis in the Complaint to conclude that eravacycline would inevitably fail, much less that these Defendants knew and concealed such information, or that these Defendants knew the results of IGNITE2 months before they disclosed them. Plaintiffs also ignore that the Individual Defendants collectively lost millions in the value of their stock holdings upon the announcement that the pivotal portion of IGNITE2 did not meet its primary endpoint. Thus, the notion that the Individual Defendants hid the truth about eravacycline for personal gain defies reason. In short, Plaintiffs have neither alleged that Defendants acted intentionally or recklessly, nor alleged that Defendants benefited in a concrete and personal way from the alleged fraud.

A. Plaintiffs fail to plead any particularized facts showing conscious misbehavior or recklessness.

Plaintiffs’ scienter allegations here amount to little more than a rehash of their falsity allegations. *See* Opp. at 33-35. Thus, these allegations fail for the same reasons as the falsity allegations, namely the absence of any well-pleaded facts to suggest that eravacycline was doomed never to pass a clinical trial or gain FDA approval. *See DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1232 (S.D. Cal. 2001) (in the absence of false or misleading statements, scienter analysis “entails the illogical inquiry into whether the defendant intended to deceive

when, in fact, there was no deception”); *see also In re Vertex Pharm. Inc. Sec. Litig.*, 357 F. Supp. 2d at 354-55 (“The existence of scientific disagreement . . . as to the potential viability of a drug in development, without more details about the substance of the debate, cannot provide the necessary strong showing of scienter.”). Ultimately, Plaintiffs cannot avoid that the Complaint fails to offer any witness, communication, meeting, report, or other evidence that Defendants knew or were reckless in not knowing that the pivotal phase of IGNITE2 would fail to meet its primary endpoint or that Defendants knew the results of the pivotal phase of IGNITE2 in May 2015. *See* Mem. at 26-28.

B. Plaintiffs’ stock sale allegations do not establish or contribute to scienter.

The Opposition devotes much space attempting to show scienter via motive and opportunity in the form of allegedly suspicious stock sales. Opp. at 26-30. But in the First Circuit, “[i]nsider trading cannot establish scienter on its own, but rather can only do so in combination with other evidence.” *Mississippi Pub. Employees’ Ret. Sys. v. Boston Sci. Corp.*, 649 F.3d 5, 29 (1st Cir. 2011); *see Brennan*, 2016 WL 4203413, at *15 (same). Given that none of the other allegations in the Complaint raises an inference of scienter (*see* Mem. at 26-31), this Court need not consider the trading allegations. In any event, even if considered, the Opposition fails to demonstrate that the alleged trades contribute to a strong inference of scienter.

First, Plaintiffs fail to plead that the Individual Defendants were in possession of material nonpublic adverse information when they traded. *Boston Sci. Corp.*, 649 F.3d at 29 (rejecting inference of scienter where allegations did not suggest that trading was based on insider information). Even if one accepts Plaintiffs’ concocted theory that eravacycline was doomed to fail, this information was public as the numerous articles Plaintiffs cite (inaccurately) for that proposition indicate. *See* SAC ¶¶ 30-34. This leaves only Plaintiffs’ unsupported (and incorrect)

claim that the Individual Defendants possessed undisclosed study results at the time of certain trades. *See supra* Section I.C.

Second, the circumstances of the Individual Defendants' trades – made pursuant to pre-established 10b5-1 plans – also counter any inference of scienter. *In re Smith & Wesson*, 604 F. Supp. 2d at 345 (“The existence of such a [10b5-1] plan generally rebuts an inference of scienter and supports the reasonable inference that stock sales were pre-scheduled and not suspicious.”) (internal quotation and quotation marks omitted). Plaintiffs contend that the Court may not consider the presence of trading plans on a motion to dismiss, relying on language from *Boston Scientific*. *Opp.* at 30. (citing *Mississippi Pub. Employees' Ret. Sys. v. Boston Sci. Corp.*, 523 F.3d 75, 92 (1st Cir. 2008)). Plaintiffs fail to address, however, that following that decision, the First Circuit and this Court have continued to consider trading plans on motions to dismiss. *See, e.g., In re Ariad Pharm., Inc. Sec. Litig.*, 842 F.3d 744, 755 (1st Cir. 2016) (considering 10b5-1 trading plan in finding no scienter based on insider trading allegations on appeal of a motion to dismiss and finding existence of plan non-dispositive only because plaintiffs alleged that plans were enacted during the Class Period); *Simon v. Abiomed, Inc.*, 37 F. Supp. 3d 499, 524 (D. Mass. 2014) (finding no scienter where “[a]ll sales during . . . the class period . . . were made pursuant to Rule 10b5-1 trading plans, some (although not all) of which were entered into prior to the class period”); *In re Smith & Wesson*, 604 F. Supp. 2d at 345.²³

Plaintiffs argue that Messrs. Thompson and Lubner entered into their trading plans “at the same time” they learned that the FDA had granted eravacycline fast-track designation and that the EMA had waived a trial of eravacycline in children for likely being ineffective, and at a time

²³ The First Circuit was also presented with a 10b5-1 plan argument in *Fire and Police Pension Ass'n of Colorado v. Abiomed, Inc.*, 778 F.3d 228, 246 n.14 (1st Cir. 2015). There, the court declined to address the argument only because the plaintiffs had failed to allege a plausible theory of scienter “even without considering those [10b5-1] plans.” *Id.* Notably, however, the court did not state that it could not consider plans on a motion to dismiss. *Id.*

when they “likely had some data” from the pivotal portion of IGNITE 2. Opp. at 28. But this is pure speculation, groping to find in hindsight some nefarious significance to the date on which Messrs. Thompson and Lubner established their trading plans. In any event, the FDA granted fast-track designation to eravacycline – by Plaintiffs’ own allegations – *nearly a year earlier*. SAC ¶ 48 (Tetraphase announced the FDA’s grant of fast-track designation in April 2014).²⁴ Furthermore, the speculation that “some” data from the pivotal portion of IGNITE2 was “likely” available in March 2015 is not only unsupported by any fact, but ignores that the study was double-blind, such that any data Defendants might have had in March 2015 was blinded and would have told them nothing. *See Abely*, 2013 WL 2399869, at *7 & n.3 (taking judicial notice that in double-blind trials, “both subjects and investigators, as well as sponsor or investigator staff involved in the treatment or clinical evaluation of subjects, are unaware of each subject’s assigned treatment”). In any event, none of Plaintiffs’ unfounded conjecture can distract from their failure to address that each of the Individual Defendants established his trading plan *before* enrollment in the pivotal portion of IGNITE2 was complete (*see* Mem. at 32-33) – *i.e.*, before Plaintiffs (wrongly) allege that Tetraphase received the results of this study (*see* Opp. at 7).²⁵

C. Plaintiffs cannot rely on generic corporate motives.

Plaintiffs’ alternative scienter theory, that Defendants “forged ahead” with IGNITE2 “in a desperate attempt to keep the Company’s rights to eravacycline and preserve its only external funding source” (Opp. at 2), is equally unconvincing. The Opposition argues that Defendants were motivated to defraud investors because (1) the Harvard License Agreement and BARDA

²⁴ While Plaintiffs reference the EMA waiver (Opp. at 28), they fail to explain its alleged significance or offer any reasoning to support their speculation that the EMA decision caused Messrs. Thompson and Lubner to enact their trading plans.

²⁵ Plaintiffs argue that, at the time Mr. Macdonald entered his 10b5-1 trading plan on November 25, 2014, scientific articles showed that eravacycline would never be an effective IV-to-oral transition therapy. Opp. at 28. As discussed, the articles Plaintiffs cite say nothing of the sort. *See supra* Section I.A.

contract both “hinged on successful milestones and trial results” (Opp. at 26, 31-32), and (2) the continued operation of Tetrphase “would also preserve [the Individual Defendants’] lucrative income . . . [and] bonuses based on the Company’s performance” (Opp. at 32-33). But courts in this Circuit routinely dismiss such ordinary corporate desires. *See, e.g., Battle Const. Co., Inc. v. InVivo Therapeutics Holdings Corp.*, 101 F. Supp. 3d 135, 141 n.6 (D. Mass. 2015) (“the desire to raise capital is “possessed by virtually all corporations and is too generic to support a strong inference of motive”); *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002) (only when “financial incentives to exaggerate earnings go far beyond the usual arrangements of compensation based on the company’s earnings” can they even “be considered among other facts to show scienter”); *In re Smith & Wesson*, 604 F. Supp. 2d at 344 (“That executives may have gained some compensation is not enough, since stock-based compensation is a common feature of pay packages . . .”).²⁶

These alleged generic motives also fail because they are implausible on their face. Tetrphase simply had no incentive to launch a futile clinical trial of eravacycline at great expense if the antibiotic was “doomed to fail” from the beginning, and courts routinely reject similar theories. *See, e.g., Vertex Pharm., Inc.*, 838 F.3d at 82 (investment in clinical trial design and performance of clinical study suggests that company “must have thought that positive results were possible”); *Gillis v. QRX Pharma Ltd.*, No. 15-4868-PAE, 2016 WL 3685095, at *30 (S.D.N.Y. July 6, 2016) (investment of resources in clinical studies known to be “doomed to fail” is not a plausible state of mind and does not support an inference of scienter); *Sapir v.*

²⁶ As is also articulated in Defendants’ opening brief (Mem. at 30), the Individual Defendants could not plausibly achieve the corporate goals that Plaintiffs ascribe to them by misleading the public because (1) their bonuses were not tied to the Company’s stock price and (2) the FDA controlled the approval of eravacycline. The Opposition notably fails to address either argument, and the cases cited therein change nothing (*see* Opp. at 33). *See, e.g., Crowell v. Ionics, Inc.*, 343 F. Supp. 2d 1, 15-16 (D. Mass. 2004) (finding strong inference of scienter where, unlike here, defendants were motivated to inflate financial results and stock prices because their compensation was based on the company’s financial performance); *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920, 944 (9th Cir. 2003) (same).

Averback, No. 14-7331-(JLL)(JAD), 2016 WL 554581, at *10-13 (D.N.J. Feb. 10, 2016) (finding implausible the conclusion that “Defendants knew all along that the Phase 3 Studies were unlikely to succeed but concealed this information in order to prolong the viability of the Company”); *In re Columbia Labs., Inc. Sec. Litig.*, No. 12-614 (FSH), 2013 WL 5719500, at *7 & n.19 (D.N.J. Oct. 21, 2013), *aff’d* 602 F. App’x 80 (2015) (citing continued investment in drug development and submission of an NDA as evidence belying scienter).²⁷

CONCLUSION

For all of the foregoing reasons, the Court should dismiss the Second Amended Class Action Complaint in its entirety, with prejudice.

Respectfully submitted,

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²⁷ The resignations of Messrs. Thompson and Lubner are insufficient to support a strong inference of scienter, and the case Plaintiffs cite (*Opp.* at 33) only confirms this. *See In re Adaptive Broadband Sec. Litig.*, No. C01-1092, 2002 WL 989478, at *14 (N.D. Cal. Apr. 2, 2002) (departure or change in position of three individual defendants “taken alone” does not support scienter, but “add[s] one more piece to the scienter puzzle” where company’s financials were being restated and company was conducting its own internal investigation).

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (“NEF”) on this 12th day of January, 2017.

/s/ Sarah L. Murphy
Sarah L. Murphy